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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,672	06/01/2001	Ryota Sugimoto	018961-054	8651

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10/16/2003

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EXAMINER
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MATHEW, FENN C

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/870,672

Applicant(s)

SUGIMOTO, RYOTA

Examin r

Fenn C Mathew

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7 and 9-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9-12,14-22 and 24-31 is/are rejected.
- 7) ☒ Claim(s) 4,13 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 4 and 13 objected to because of the following informalities: The aforementioned claims refer back to cancelled claim 3. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-x are rejected under 35 U.S.C. 102(e) as being anticipated by Shanley (U.S. 6,293,967). Referring to claim 1, Shanley discloses an implantable tubular device having a deformable portion (40) on the peripheral surface (see fig. 12a), with the deformable portion forming a predetermined angle (inherently) with respect to the axial direction, and being easy to deform in comparison with a remainder part of the device the deformable portion being formed as a groove on an inwardly and outwardly facing direction of the tubular device.
4. Referring to claim 2, Shanley discloses an implantable tubular device having a diameter so that the device can be inserted into a lumen, the device comprising a

plurality of wavy annular member each formed of a wavy element and arranged in an axial direction (see fig. 12a), connection portions (84) connecting the wavy annular members to each other in an axial direction of the device, wherein each of the wavy annular members have free bent portions (118, 122) not connected to other wavy annular members, a deformable portion (40) inherently forming a predetermined angle with respect to the axial direction of the device, the deformable portion being formed on one of the free bent portions in such a way that the deformable portion crosses the wavy annular member (partially crosses).

5. Referring to claim 5, Shanley discloses the deformable portions forming an angle of 90 degrees with the axial direction.

6. Referring to claim 6, Shanley discloses the deformable portions formed so that when they are prolonged, the deformable portions go around a periphery of the device (inherently since deformable portions are circumferentially in a line).

7. Referring to claim 10, Shanley discloses the device being a stent.

8. Referring to claim 20, Shanley discloses the device consisting of a stent having a frame structure, with the deformable portions on the frame structure.

9. Referring to claim 21, Shanley discloses the device consisting of a stent having a frame structure, with the plurality of deformable portions on the frame structure.

10. Referring to claim 22, Shanley discloses the grooves formed on the inner and outer surfaces.

11. Referring to claim 32, Shanley discloses an implantable tubular device formed substantially tubular and having a diameter so set that the device can be inserted into a

lumen, the device comprising a plurality of annular members arranged in an axial direction of the device and connection portions each connecting the annular members to each other in the axial direction of the device, wherein each of the annular members have deformable portions forming a predetermined angle with respect to the axial direction of the device and being more easily deformed than a remainder of the device, the deformable portions being formed as grooves provided on an inner and outer surface of the tubular device. (See discussion above).

12. Referring to claim 33, Shanley discloses an implantable tubular device having a plurality of deformable portions formed on a peripheral surface of the tubular device, with the deformable portions forming a predetermined angle with respect to an axial direction of the tubular device and being more easily deformed in comparison with a remainder part of the tubular device, the tubular device being comprised of a plurality of annular units, with adjacent annular units connected together by joining portions, the annular units each being comprised of at least one wavy annular member, the deformable portions being formed as grooves provided on the wavy annular members.

13. Referring to claim 34, Shanley discloses the grooves provided on both an inner and outer surface.

***Claim Rejections - 35 USC § 103***

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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15. Claims 9, 11-12, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley. Referring to claims 9 and 24, the feature of having the interval between deformable portions in an axial direction be 0.01-1 mm is a matter of design choice within the knowledge of one with ordinary skill in the art, as the skilled artisan would choose a distance based on its suitability for the intended purpose, and the applicant has failed to establish criticality for the claimed range, and the distance as disclosed by Shanley would suffice absent any unexpected or undesired results.

16. Referring to claims 11-12 and 25-26, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore this limitation has not been given patentable weight. The skilled artisan would choose a manner in which to form the device based on suitability and desired results.

17. Claims 14-19 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Alt et al. (U.S. 5,876,449). Referring to claim 14 and 27, Shanley discloses the claimed invention except for the device carrying a medicine. Alt teaches that it is well known and advantageous to provide a medicinal coating to stents (column 8). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the stent of Shanley with a medicinal coating as taught by Alt in order to deliver medicine to areas of the body once the device has been implanted.

18. Referring to claim 15 and 28, Shanley discloses the claimed invention except for having at least one part of the outer surface coated with a coating material made of a biodegradable material. Alt teaches a coating comprising a biodegradable material (col.

6, lines 59-64), which can be used for a stent (col. 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Shanley with the coating taught by Alt in order to provide a more biocompatible implant that will not cause harm during degradation.

19. Referring to claim 16 and 29, Shanley discloses the claimed invention except for having at least one part of the outer surface of the deformable portion coated with a coating material made of a biodegradable material. Alt teaches a coating comprising a biodegradable material (col. 6, lines 59-64), which can be used for a stent (col. 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the outer surface of the deformable portion of the device disclosed by Shanley with the coating taught by Alt in order to provide a more biocompatible implant that will not cause harm during degradation.

20. Referring to claim 17 and 30, Shanley as modified above discloses the coating carrying a medicine (col. 8).

21. Referring to claim 18 and 31, Shanley, as modified by Alt discloses a coating material formed of a biodegradable material to which a medicine is added (col. 8).

***Allowable Subject Matter***

22. Claims 4 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The feature of having the grooves at a depth of 5-50% is neither anticipated nor obvious over the prior art of record.

### ***Response to Arguments***

23. Applicant's arguments with respect to claims 1, 2, and 32-33 have been considered but are moot in view of the new ground(s) of rejection. Specifically, the claimed language still fails to make clear the location and structure of the grooves. The grooves of Shanley can still be considered to be on an outward or inward facing portion of the device. The lack of claim language addressing groove depth in the independent claims makes the claims readable in the broadest reasonable light on Shanley. With regards to claim 2, the claim language states that the deformable portion crosses the wavy annular member at one of the free bent portions. As best understood by the examiner, the limitations are met by Shanley, since the grooves partially cross the wavy annular member at a portion not connected to other wavy members.

### ***Conclusion***

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lootz        U.S. 6,613,080

Kim         U.S. 6,613,081

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.



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The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
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September 22, 2003